

REMARKS**1. The Amendments and the Support Therefor**

No claims have been canceled, four new claims (61-64) have been added, and claims 31, 36, 40, 50, 51, and 52 have been amended to leave claims 24-34, 36-43, and 46-64 in the application. A PTO-2038 for any newly-submitted claims in excess of the amount previously paid for should accompany this Response, as per 37 CFR §1.16(b)-(d), with the fee due being calculated as follows:

FEE CALCULATION

| For | Already Paid | No. Extra | Rate (SMALL ENTITY) | Fee (SMALL ENTITY) |
|--------------------|--------------|-----------|---------------------|--------------------|
| Total Claims | 38 - 34 = | 4 | x \$25 = | \$100 |
| Independent Claims | 7 - 7 = | 0 | x \$100 = | \$0 |
| Total: | | | | \$100 |

No new matter has been added by the amendments or new claims. For your convenience, following is a summary cross-referencing certain amendments and the new claims to exemplary portions of the specification and/or drawings disclosing the recited structure. A more detailed explanation of these amendments and new claims is provided where it is thought to be helpful:

Claim 31 is amended to correct dependency.

Claim 36 finds support in Figs. 6-7 and page 12 line 20-page 13 line 8.

Claim 40 finds support in claim 24.

Claim 50 is amended to correct an informality regarding antecedent basis.

Claim 51-52 find support in claim 24.

Claim 61-63 find support in, for example, Fig. 1.

Claim 64 finds support in (for example) Figs. 6-7 and page 7 line 17-page 9 line 3.

Further comments regarding the new claims are set out below at Section 8 below.

2. Page 2 of the Office Action: Rejection of Claim 31 under 35 USC §112(2)

Claim 31 has been amended to obviate the §112(2) rejection.

3. Page 2 of the Office Action: Rejection of Claims 24, 27-29, 31, 32 and 50-52 under 35 USC §102(e) in view of U.S. Patent 5,527,338 to Purdy

Kindly reconsider these rejections. Regarding independent claim 24, and amended independent claims 51 and 52, these state that the stent is formed from and defined by a single unitary length of wire. Despite the Examiner's arguments, the *Purdy* stent is clearly not formed from and defined by a single length of wire: as seen in Figs. 1 and 2 of *Purdy*, it has two coiled lengths joined by three parallel lengths. Further, *Purdy* clearly states that it is formed of multiple lengths, see column 3 lines 25-28:

The present invention relates to a multi-element intravascular occlusion device comprising at least one lead element attached to at least one anchoring element by at least one fiber.

Also column 5 lines 37-39:

The device 10 comprises an anchoring element 12 and a lead element 14 connected by fibers 16, wherein both elements are coils.

Also column 6 line 10 onward:

The attachment of the fibers 16a, 16b, 16c to the anchoring element 12 and the lead element 14 may be achieved by solid or mechanical means. Solid attachment may be achieved by use of solder or glue materials or by melding or fusion of the two. Mechanical attachment may be achieved by tying or twisting a fiber 16 onto the other elements. The attachment of the elements will be a function, to some extent, of the desired application.

It is accepted that during examination, the USPTO must interpret the claims using their broadest reasonable interpretation (MPEP 2111). Words in a claim are therefore given their plain meaning unless a contrary definition is provided in the specification (MPEP 2111.01). Under no reasonable interpretation can *Purdy* be regarded as "formed of" a single length of wire; *Purdy* explicitly states that it is not. Further, under no reasonable interpretation can *Purdy* be regarded as "defined by" a single length of wire: it has multiple branching lengths/paths, rather than a single length. In this respect, it is notable that the "plain meaning" to be applied to words in a claim is the meaning applied by those of ordinary skill in the art (MPEP 2111.01), and *Purdy* notes that it has multiple lengths. See column 5 line 66-column 6 line 3:

A plurality of fibers 16a, 16b, 16c serve as a means for connecting the anchoring element 12 and the lead element 14. Fibers 16 are typically between 3 and 30 mm in length. However, they may be any length suitable for the application.

Here, each of the *Purdy* fibers 16a-16c is stated to have its own length. Even when the fibers 16a-16c are joined to the opposing coils, they will define parallel lengths rather than a single length as recited. In summary, regarding *Purdy* as being formed from and defined by a single unitary length of wire certainly applies a broad interpretation of the terms of the claims as per MPEP 2111 – but it is not a reasonable one, particularly when *Purdy* explicitly states it is not “formed from” a single length, and both plain meaning and *Purdy*’s own statements show that *Purdy* is not “defined by” a single length.

The Examiner notes that *Purdy* discloses in Fig. 4 that the stent may have only 2 connecting fibers attached to the ends of each coil, and it would have been obvious to provide this arrangement in *Purdy*’s Figs. 1 and 2 to attain the claimed arrangement. However, even here *Purdy*’s arrangement would not be *formed from* a single length: as the Examiner’s own comments note, attachment of multiple lengths is needed. Further, even assuming that the argued arrangement was formed of a single length of wire with its opposing ends attached, there is no true motivation provided by *Purdy* or any other reference to use such an arrangement: since *Purdy* teaches two coils (which must necessarily have some rigidity in order to retain a coiled shape), connected by fibers/leads (which must lack rigidity in order for one coil to flow downstream from the other and “unspring” to deploy), what advantage would one of ordinary skill see in attempting to form *Purdy*’s Figs. 1-2 of a single member? How could one even form such a unitary member having such varying rigidity over its length, such that two parts of its length would retain a coiled shape and two intervening parts would remain flexible? Or, more relevant to the §103 analysis, *why* would an ordinary artisan see any advantage to trying to form *Purdy*’s Figs. 1-2 of a single unitary piece of wire, particularly in view of the difficulty (if not impossibility) of constructing *Purdy* from a single wire, and in view of *Purdy*’s own discussion of forming the stent of connected lengths?

It is also notable that in any event, *Purdy* does not disclose or suggest any stent wherein the resulting wire turns of the expanded anchor are coplanarly disposed, as recited in claims 24, 50, and 51. Comparing (for example) Figs. 1-2 of *Purdy*, in Fig. 1, the anchor part 12 is a coil wherein the turns are displaced in *different planes* along the axis of the coil (Fig. 1). In Fig. 2,

the coil 12 simply “unsprings,” with the connecting fibers 16a-16c then causing the length of the coil 12 to bend into the configuration shown in Fig. 2, wherein the turns of the coil 12 are *still* in different planes (these planes intersecting at the center of the circle/curve of the coil 12 in Fig. 2). Consider: how is the coil 12 of Fig. 1 – which, again, must have some rigidity to retain a coiled shape – going to deploy in such a manner that its individual turns *compress* from the arrangement of Fig. 1 so that they all rest in substantially the same plane, and so that these turns then laterally displace from the axis of the coil so that they adopt the form recited in claims 24, 50, and 51?

In summary, because *Purdy* is not defined by and formed from a single length of wire, there is no true motivation for forming *Purdy* of a single length of wire as recited in claims 24, 50, and 51. *Purdy* additionally does not include laterally displaced coplanar turns as recited in claims 24, 50, and 51. Thus, these claims and their dependent claims 25-34, 43, 50, and 62-64 are allowable.

4. Page 5 of the Office Action: Rejection of Claims 36-38 under 35 USC §102 in view of U.S. Patent 4,352,542 to Tydings

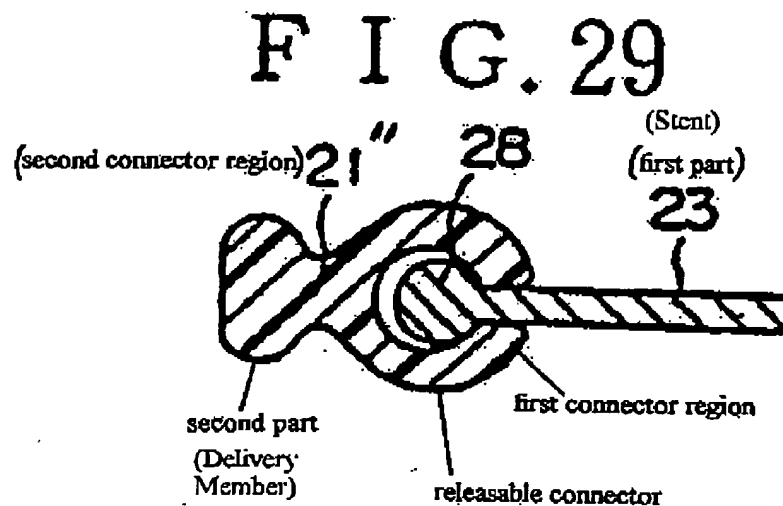
Claim 36 has been amended to recite that the second connector region does not have the shape memory effect of the first region, and this arrangement is neither shown in nor suggested by *Tydings*, wherein both regions have the same shape memory effect. Further, there is no motivation to modify *Tydings* to attain the claimed arrangement because *Tydings* would not work as intended to grasp inserted cables if both regions did not change shape at the trigger temperature (see column 3 lines 18-30).

5. Page 5 of the Office Action: Rejection of Claims 40, 41, 43, and 46 under 35 USC §103(a) in view of U.S. Patent 5,527,338 to *Purdy* and U.S. Patent 5,192,301 to *Kamiya et al.*

Claim 40 has been amended to reflect the limitations of claim 24, and thus the claimed arrangement is submitted to be novel and unobvious for the reasons discussed in Section 3 of this

Response: since claim 40 does not describe or suggest the *Purdy* stent, a combination of *Purdy* and *Kamiya* will not result in the claimed invention.

In addition, *Kamiya* does not disclose the connector recited in claim 40, giving another reason why a combination of *Purdy* and *Kamiya* would not result in the claimed invention. To repeat prior arguments, the Examiner's interpretation of the recitations of claim 40 to read on *Kamiya* is not reasonable. The Examiner "reads" claim 40 onto *Kamiya* as follows:



Initially, claim 40 (as with claim 36) recites that the second connector region is *adapted to be secured* to the second part. However, in *Kamiya*, the alleged second connector region is not adapted *to be secured* to the second part; it *is secured/connected*, and is never disconnected during usage. Stated more simply, no reasonable artisan would regard the alleged second connector region as being "adapted to be secured" to the alleged second part when the two are *integrally formed*, since no one (whether in this field of art or any other) describes integrally formed/connected members as being "adapted to be secured" to each other. If the alleged second connector region 21" was somehow not integrally connected to the second part/leftmost plug of *Kamiya*, the claim interpretation might be reasonable; but in the present situation, the alleged

parts would no more be considered to be "adapted to be secured" to each other than one would regard the top half of this page to be "adapted to be secured" to the bottom half.

Second, claim 40 (as with claim 36) recites that the stent and delivery member are *separate from* (but adapted to be secured to) the first and second connector regions. *Kamiya* plainly does not meet this requirement: its alleged "delivery member" or "second part" is plainly connected to its alleged "second connector region." The Examiner points to definitions from Dictionary.com that allegedly support the Examiner's interpretation, with the Examiner stating that "separate" merely means "distinct" or "dissimilar," and that it can encompass a meaning wherein *Kamiya*'s second part/delivery member (as shown in the foregoing drawing) would be regarded as "separate from" the illustrated second connector region. However, the Examiner's definitions are misleading because they are selectively chosen from the overall Dictionary.com definition. A fair and correct reading requires that the full Dictionary.com definition be considered, and the parts omitted by the Examiner are seen to be contrary to the Examiner's argument:

Separate

adj. (spr-t, sprt)

1. Set or kept apart; disunited: *Libraries often have a separate section for reference books.*
2.
 - a. Existing as an independent entity.
 - b. often **Separate** Having undergone schism or estrangement from a parent body: *Separate churches.*
3. Dissimilar from all others; distinct: "a policeman's way of being separate from you even when he was being nice" (John le Carré).
4. Not shared; individual: *two people who held separate views on the issue.*
5. *Archaic.* Withdrawn from others; solitary.

Looking at the definition as a whole, it is abundantly clear that "separate" refers to unjoined parts. Comparing the foregoing definition to the foregoing drawing, the alleged "second part" of *Kamiya* is in no way "set or kept apart" from, "disunited" from, "existing as an independent entity" than, or "individual" from the alleged "second connector region": *Kamiya* plainly connects them as an integral part. *Kamiya* therefore does not disclose the connector recited in claim 40, and thus a combination of *Kamiya* and *Purdy* would not result in the claimed invention, and the rejection should be withdrawn.

Further, it is also notable that claim 36 – which contains the same language as claim 40 – was previously rejected in view of *Kamiya* (see May 24, 2004 Office Action), but Applicant then argued against these rejections (see Section 3 of the last Response of August 11, 2004), and then these rejections were withdrawn (see the present Office Action of October 12, 2004). Why were the arguments for the allowability of claim 36 over *Kamiya* found persuasive, and the rejections of claim 36 withdrawn – but now *Kamiya* is applied to claim 40, *which contains the same limitations*? This is inconsistent.

6. Page 7 of the Office Action: Objection to Claims 30 and 42

The indication that objected claims 30 and 42 are allowable if rewritten in independent form is noted and appreciated. It is requested that the objections be placed in abeyance pending reexamination of the application in view of the foregoing comments.

7. Page 7 of the Office Action: Allowance of Claims 1-16

The indication that claims 39, 47-49 and 53-60 are allowable is noted and appreciated.

8. New Claims 60-64

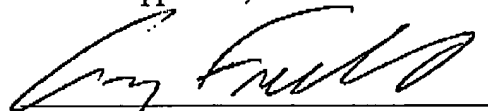
New claims 60-63, which amplify the points made in Section 3 of this Response, are submitted to be allowable because *Purdy*, even if formed of a single length of wire having its ends joined (as argued by the Examiner), would then not have two free ends, nor is there any true motivation to construct such an arrangement.

New claim 64 is submitted to be allowable because the matter recited therein is not disclosed by *Tydings*, nor is it obvious in view of *Tydings*, particularly since *Tydings* is not in the medical field nor in a field analogous thereto, and thus one of ordinary skill would not look to the *Tydings* field of fiberoptic communications and fiberoptic splicing to look for solutions to problems addressed by the device of claim 64.

9. In Closing

If any questions regarding the application arise, please contact the undersigned attorney. Telephone calls related to this application are welcomed and encouraged. The Commissioner is authorized to charge any fees or credit any overpayments relating to this application to deposit account number 18-2055.

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ATTACHMENTS:

- PTO-2038 (\$160)